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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,192	06/06/2002	Brigitte Desiree Alberte Colau	B45194	8137

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SMITHKLINE BEECHAM CORPORATION
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EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,192	COLAU ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-56,77,78,92,94-115,120 and 146 is/are pending in the application.
- 4a) Of the above claim(s) 40-56,77 and 78 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 94-115,120 and 146 is/are allowed ~~table~~.
- 6) ☒ Claim(s) 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed 20 December 2006.

Claims 1-39, 57-76, 79-91, 93, 116-119, and 121-145 have been cancelled. New claim 146 is added. Claims 40-56, 77, 78, 92, 94-115, 120, and 146 are pending. Claims 40-56, 77, and 78 are withdrawn. Claim 92 is under final rejection. Claims 94-115, 120, and 146 are allowable.

During a telephonic interview on 16 November 2006 between Examiners, Humphrey and Parkin, and Applicants' Representatives, Ms. Hecht and Dr. Crepin, Ms. Hecht and Dr. Crepin agreed to amend the claims to distinguish the claimed invention over the prior art. Examiners advised Applicants to clarify the structural limitations or any limitations that result in a structural difference between claimed invention and prior art.

Response to Amendment

Claim Rejections - 35 U.S.C. §112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 82-91, 93, 116-119 and 121-145 under 35 U.S.C. §112, second paragraph, as being indefinite is **withdrawn** in view of the claim cancellation.

The rejection of claims 94-115 and 120 under 35 U.S.C. §112, second paragraph, as being indefinite is **withdrawn** in view of the claim amendment deleting the phrase "a substantially single variant."

The rejection of claim 92 under 35 U.S.C. §112, second paragraph, as being indefinite is **maintained** because the claim contains the indefinite phrase "substantially a single variant" in line 3.

The rejection of claims 82-86, 89, 93, 94, 116, 117 and 142 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the claim cancellation or amendment.

The rejection of claim 92 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is **maintained**. Applicants allege that the phrase "substantially single variant" has been deleted to render this ground of rejection moot. However, claim 92, in line 3, recites "or substantially a single variant," of which the specification shows that Applicants are not in possession of at the time of invention.

The rejection of claims 82-88, 93, 95, 96, 99-119, 121, 122, and 125-144 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope is **withdrawn** in view of the claim cancellation or the amendment that renders claims 94-115 to read on a vaccine composition comprising a live attenuated human rotavirus population comprising a

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single variant defined by six mutations in the nucleotide sequence encoding VP4 and VP7 proteins.

The rejection of claim 92 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope is **maintained**.

Examiner's rejection in the Action mailed on 17 October 2006 is as follows:

Enablement is considered in view of the Wands factors (MPEP §2164.01(a)). The claims are drawn to a vaccine composition comprising a live attenuated human rotavirus population defined by a nucleotide sequence encoding at least one of VP4 and VP7, in which the VP4 or VP7 gene comprises at least one substitution. The broad claims encompass any single mutation in either VP4 or VP7 region.

The art of rotavirus vaccine development is highly uncertain and unpredictable in terms of its efficacy. The major problem with rotavirus vaccine is intussusception (Glass, 2006). Any other rotavirus variant that does not contain the six mutations in VP4 and VP7 regions as P43 has not been assessed for its efficacy and risk for clinical use.

The only working example disclosed in the specification is P43. There is no specific guidance regarding the safety and efficacy of the variants that contain only one of the mutations present in P43. A live attenuated rotavirus vaccine is not considered routine in the art and without sufficient guidance to protection against rotavirus infection by any single point mutant, the experimentation left to those skilled in the art is undue or unreasonable under the circumstances.

Applicants allege that claim 92 has been amended to recite both amino acid mutations in the VP4 and VP7 regions. However, claim 92, as amended, still is drawn to a vaccine composition comprising a live attenuated human rotavirus comprising at least one of VP4 and VP7, wherein the VP4 contains Phe at position 167 and VP contains Met at position 202. The claim, as amended, reads on any human rotavirus variant that contains only one of the recited amino acid residues, which are not enabled by the specification for reasons set forth in the previous Action as indicated above. The

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only human rotavirus variant supported and enabled by the specification, P43, contains six amino acid changes corresponding to the six nucleic acid mutations. See page 17, Table 3.2. Claim 92 encompasses other human rotavirus variants that have unpredictable efficacy. Therefore, claim 92 remains rejected as containing subject matter not described in the specification commensurate in scope of the invention.

Claim Rejections - 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 82-85, 95, 96, 99, 100, 113-115, 121, 122, 125, 126 and 132 under 35 U.S.C. §102(b) as being anticipated by Burke *et al.* (US 5,932,223) is **withdrawn** in view of the claim cancellation or the amendment of claim 95 to depend from claim 94.

The rejection of claims 82-85, 113-115, and 139-141 under 35 U.S.C. §102(e) as being anticipated by Hoshino *et al.* (US 2002/0058043) is **withdrawn** in view of the claim cancellation or the amendment of claim 95 to depend from claim 94.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 82-85, 109, and 135 under 35 U.S.C. §103(a) as being obvious over Hoshino *et al.* (US 2002/0058043) in view of Chen *et al.* (US 6,552,024) is **withdrawn** in view of the claim cancellation or the amendment of claim 95 to depend from claim 94.

The rejection of claims 82-85, 101-104, 106, 108, 110, 112, 127-130, 134, 136 and 138 under 35 U.S.C. §103(a) as being obvious over Hoshino *et al.* (US 2002/0058043) in view of Tsutsumi *et al.* (US 4,152,421) is **withdrawn** in view of the claim cancellation or the amendment of claim 95 to depend from claim 94.

The rejection of claims 82-85, 105, 107, 111, 131, 133 and 137 under 35 U.S.C. §103(a) as being obvious over Hoshino *et al.* (US 2002/0058043) in view of Tsutsumi *et al.* (US 4,152,421) and further in view of the Therapeutic Goods Administration in the Department of Community Services and Health in Australia (1991) is **withdrawn** in view of the claim cancellation or the amendment of claim 95 to depend from claim 94.

The rejection of claims 82-91, 93, 94, 116-120 and 142-145 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being

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obvious over Hoshino *et al.* (US 2002/0058043) is **withdrawn** in view of the claim cancellation or the amendment.

The rejection of claim 92 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Hoshino *et al.* (US 2002/0058043) is **maintained**. Applicants allege that the phrase "substantially single variant" has been deleted to render this ground of rejection moot. However, claim 92, in line 3, recites "or substantially a single variant," which is anticipated by or obvious over Hoshino *et al.* (US 2002/0058043).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
30 March 2007



Louise Humphrey, Ph.D.
Assistant Examiner